

JUN 27 2014

K141413
Page 1 of 2

Appendix # 3

510(k) Summary/Statement Certification

Re: K141413

CHECK ONE ONLY:

☒ **1.510(k) Summary.** Attached is a summary of safety and effectiveness information upon which an equivalence determination could be based.

☐ **2.510(k) Statement.** I certify that, in my capacity as

Vice President, Manufacturing of Capintec, Inc.

I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR20.61.

Mary Anne Yusko

[Signature*]

Mary Anne Yusko

[Typed or Printed Name]

April 2, 2014

[Date]

* Must be signed by a responsible person or the firm required to submit the premarket notification (e.g., not a consultant for the 510(k) submitter).

K141413
Page 242



CAPINTEC, INC.

April 3, 2014

RE: Summary of Safety and Effectiveness Information for the Capintec CRC PC series.

Capintec's CRC PC Smart Chamber series dose calibrators are designed for measurement of radioactive materials used in nuclear medicine, therapy, and research applications. The unit is intended for use by trained nuclear medicine technologists, nuclear medicine physicians, radiopharmacists, or medical physicists for diagnostic and therapeutic applications.

The CRC PC series has the same principles of operation, same basic functionality, and same detector technology as the predicate device, CRC 55t series. The basic detection, measurement process, design concepts, calculations, algorithms, and response remain the same as the predicate device. There are no differences in intended use or effectiveness. The CPC PC Smart Chamber replaces the touchscreen user interface of the predicate device with a laptop or network PC.

The predicate devices, Capintec dose calibrator lines, upon which the CRC PC is based, have a long history of over 30 years of safe, reliable, and effective use in the field. The addition of a larger PC interface enhances safety and effectiveness by providing improved visibility and easier alphanumeric data input. The CRC PC family of dose calibrators have been tested and approved to the following EMC and electrical safety standards for medical equipment:

IEC 60601-1-2 (2007): 3rd Edition: Medical Electrical Equipment – Part 1 General Requirements for Safety – Section 1.2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

IEC 60601-1 Issued: 2005 Ed:3: Medical electrical equipment Part 1: General requirements for basic safety and essential performance

IEC 60601-1-6 2010 3rd Edition: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

AAMI ES60601-1 Issued: 2005: Medical electrical equipment Part 1: General requirements for basic safety and essential performance

CAN.CSA-C22.2 No. 60601-1:08: Issued: 2008: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 27, 2014

Capintec, Inc.
% Ms. Mary Anne Yusko
VP, Development and Regulatory Affairs
620 Alpha Drive
PITTSBURGH PA 15241

Re: K141413

Trade/Device Name: Capintec CRC PC with Smart Chamber Series
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide does calibrator
Regulatory Class: II
Product Code: KPT
Dated: May 21, 2014
Received: May 29, 2014

Dear Ms. Yusko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

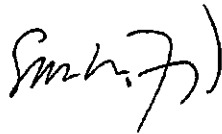
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K141413

Device Name: CRC PC with Smart Chamber

Indications for Use: The CRC PC Smart Chamber series is intended to be used by qualified nuclear medicine technologists, nuclear medicine physicians, and radiopharmacists to measure a wide range of radiopharmaceuticals and radioactive materials, including high energy beta and gamma emitters for diagnostic and therapeutic applications. It is also designed for use by trained medical physicists for diagnostic and therapeutic applications including measurement of the output of most radioactive brachytherapy sources, including LDR, HDR, and IVBT sources. All brachytherapy sources must be measured in the appropriate source holder. This device is also used in numerous research applications for measurement of radioactive materials.

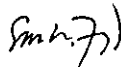
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)



(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k) 141413

Page 1 of 1